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A retrospective outcomes review of patients with idiopathic normal pressure hydrocephalus treated with a low flow valve system☆

Phillip G. St. Louis, MD, FACS *, Sheena Boodoo, MD, Tara Batz, PA-C, Jennifer Clements-Lipofsky, BS

Associates in Neurosurgery, Orlando, FL, USA

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ABSTRACT

Accepted treatment of patients with Idiopathic Normal Pressure Hydrocephalus (INPH) dictates the placement of a Ventriculoperitoneal (VP) shunt. Selection of a valve regulated system for implantation is usually determined by the treating surgeon. Data regarding the efficacy of a Low Flow Valve (LFV) are sparse. The use of this type of system may be of benefit in patients with INPH. Data from fourteen patients in the Florida Hospital NPH Program Registry with placement of a Low Flow Valve were retrospectively examined. All patients completed baselines studies to quantify gait disturbance, cognitive dysfunction, and ventriculomegaly (Evan's Ratio). Studies were repeated post three day external lumbar drain, as well as 6, 12, and 24 months post shunt placement. Significant improvement was noted in gait (Berg Balance Score) at six months and one year post shunt placement. Patients improved from a "medium" fall risk to a "low" fall risk. Significant improvement in NAB was noted at 2 years of follow up, improving from "mildly impaired" to "average". Evan's ratio was stable throughout the study. There were no instances of over drainage or shunt infection. One shunt obstruction which necessitated surgical intervention was observed. Objective improvement in BERG and NAB appears to provide conclusive evidence of efficacy in this small group of patients with INPH treated with placement of an LFV and followed for two years. The absence of over-drainage as a related complication in this small group is encouraging.

Introduction

Accepted treatment of patients with Idiopathic Normal Pressure Hydrocephalus (INPH) dictates the placement of a Ventriculoperitoneal (VP) shunt. Selection of a valve regulated system for implantation is usually determined by the treating surgeon. The use of a programmable Differential Pressure valve system is currently a popular choice, however problems related to over-drainage, MRI compatibility, and frequent reprogramming are not uncommon with these systems. Data regarding the efficacy of a Low Flow Valve (LFV) System in the treatment of patients with Idiopathic Normal Pressure Hydrocephalus (INPH) are sparse. The use of this type of system may be of benefit in patients with INPH. This paper provides evidence for the usefulness of the LFV System in the treatment of patients with this disorder by examining pre-operative and post-operative outcome data which address hallmark indicators of INPH such as magnetic gait, cognitive dysfunction, and ventriculomegaly. This study is a prelude to a larger randomized trial comparing its effectiveness to a Differential Pressure valve system. (See Fig. 2.)

Methods

Data from fourteen patients in the Florida Hospital NPH Program Registry with placement of a Low Flow Valve were retrospectively examined. Patient history was reviewed to exclude secondary causes of hydrocephalus, and to include only those patients with suspected INPH. All patients completed an MRI (CT if indicated), BERG Balance Scale (BERG) and Neuropsychological Assessment Battery (NAB) at baseline then 6 and 12 months postoperatively.

To quantify INPH hallmark gait disturbances such as gait apraxia, hypokinesia, and disequilibrium [1] the BERG (BERG) Balance Scale was utilized. The BERG Balance Scale is a standard reproducible assessment which assigns a numeric value (1–56) to patients performing balancing tasks inclusive of sitting to standing, standing on one foot, standing with feet together, and standing/sitting unsupported [2]. Though in published literature the Timed Up and Go (TUG) test was administered to evaluate gait in patients with NPH [3], the BERG by definition was designed to measure balance specifically among older individuals for quantitative descriptions of function and fall risk in clinical practice and research.

The principle cognitive symptoms seen in INPH are suggestive of a subcortical dementing process, including slowing of thought, inattentiveness, apathy, encoding and recall problems, as well as impaired executive functions [3,4]. When possible, quantifiable measures of cognitive performance (neuropsychological tests) should be used [4].

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* Corresponding author at: 532 Virginia Dr., Orlando, Fl 32803. Tel.: +1 407 898 8644; fax: +1 407 898 8646.
E-mail address: stlouis@ain.md (P.G. St. Louis).

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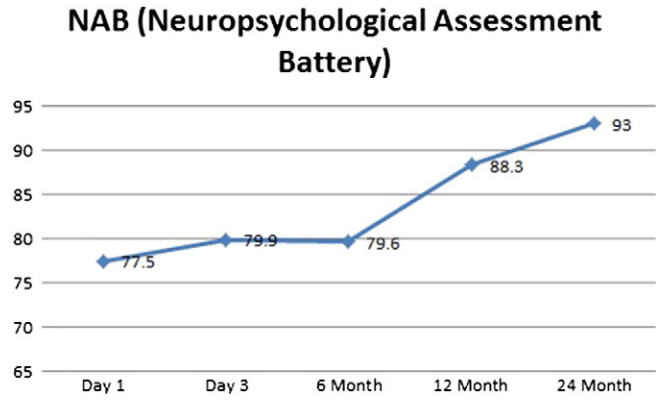

Fig. 1. NAB scores associated with improvement at baseline (Day 1), post ELD (Day 3), as well as 6, 12, and 24 months post operatively.

The Neuropsychological Assessment Battery (NAB) was the predominant cognitive measuring tool in this study. The NAB is a comprehensive, modular battery of Neuropsychological tests developed for the assessment of a wide variety of cognitive skills and functions in adults aged 18–97 with known or suspected disorders of the central nervous system [5]. The modules test attention, language, memory, spatial, and executive scores to generate a numerical Total Screening Index.

Brain Magnetic Resonance Imaging (3 T MRI) was utilized to identify ventriculomegaly. The Evan's Ratio, which is defined as the maximal width of the frontal horns measured at their extreme to the maximal biparietal diameter was documented. CSF flow studies through the Aqueduct of Sylvius such as Stroke Volume and Stroke Velocity were additionally documented components, these findings will be discussed in a future publication.

Upon admission to the Florida Hospital NPH Program, the three evaluations (BERG, NAB, and MRI) were completed at baseline upon hospital entry. A Lumbar Sub-Arachnoid drain was then inserted and CSF was drained (10 ml/h) over 48–72 h. Repeat testing (BERG, NAB, MRI) was then completed and the lumbar drain was removed before the patient was discharged on Day 3. Baseline testing was compared to Day 3 Data, and a likelihood of benefit was assigned subsequent to a round table discussion comprised of the specialists who treated the patients. Repeat testing (BERG, NAB, and MRI) was completed 6, 12, and 24 months post shunt placement. Patients were also clinically evaluated with CT scans between testing intervals to address over drainage or other shunt related complications.

A Flow Regulating Ventriculoperitoneal shunt (Integra NPH Low Flow Valve System™) was placed in all patients. These Flow

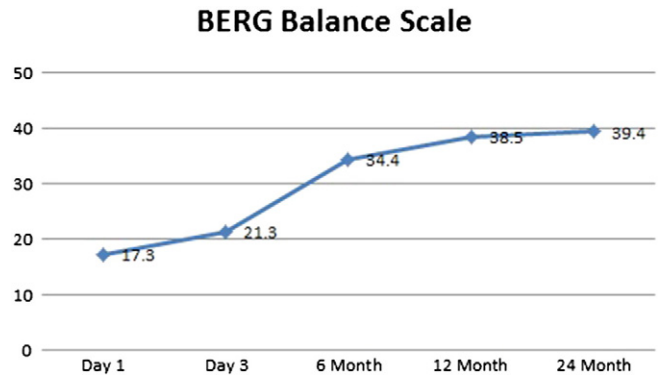

Fig. 2. BERG Balance Scores associated with improvement at baseline (Day 1), post ELD (Day 3), as well as 6, 12, and 24 months post operatively.

Table 1
Patient co-morbidities in 14 patients treated with a Low Flow Valve.

Comorbidities	Occurrence within patients
Alcoholism	1
Anxiety Disorder	2
Arthritis	1
Cancer	1
Cardiac Disease	3
Cerebral Aneurysm	1
Depression	1
Diabetes	2
High Cholesterol	3
Hypertension	10
Parkinson's Disease	3
Stroke	2

Regulating valves use variable resistance to the flow of CSF at the physiological rate of CSF production. This device does not have various valve settings, and is designed to minimize potential postural and vasogenic overdrainage situations. The Integra NPH Low Flow Valve System™ flow rate is 8–17 ml/h. All shunt procedures were done by one surgeon (PSL), utilizing the same surgical team.

Nine patients were retested (BERG, NAB, MRI) at six months and eight patients [were retested] (BERG, NAB, MRI) at twelve months post shunt placement. Six patients were lost to follow up. Seven patients were retested (BERG, NAB, MRI) at twenty-four months post shunt placement, and serve as the basis of this paper. One patient was excluded from two year data due to shunt malfunction one year post operatively and subsequent crossover to a Differential Pressure valve system.

Results

Of the 14 patients who had initial baseline evaluation (BERG, NAB, MRI) and placement of the LFV, there were 7 women and 7 men. Their ages ranged from 63 to 87 years (mean 77.7 years). Co-morbidities are listed in Table 1, and were as expected in this patient population. In this group of patients with placement of the LFV, there were no instances of shunt infection or over drainage during the period of this study. Five patients were lost to follow up and one patient withdrew due to an ischemic stroke. One patient developed recurrence of symptoms after his one year evaluation and was returned to surgery at which time the valve was found to be obstructed. This patient was crossed over to a Differential Pressure valve and removed from further data collection. There was no instance of over drainage. All follow ups were routine and additional monitoring was not necessary.

Initial baseline testing in 14 patients revealed mean scores of BERG: 17.3 and NAB: 77.5. Day three of testing in 14 patients subsequent to lumbar drain placement and prior to shunt placement was BERG: 21.3 and NAB: 79.9. Six month data in 9 patients post shunt placement were BERG: 34.4 (99% improvement) and NAB: 79.6 (2.70% improvement). One year data in 8 patients were BERG: 38.5 (122% improvement) and NAB: 88.3 (13.93% improvement). Two year data in 7 patients were BERG: 39.4 (127% improvement) and NAB: 93 (20% improvement).

Discussion

The data from this retrospective study of 14 patients indicate that a flow regulated valve system may significantly improve the outcome in INPH.

Gait

A BERG Balance Score change of 4 points is needed to be 95% confident that true change has occurred if patients score within 45–56

initially, 5 points if they score within 35–44, 7 points if they score within 25–34 and, finally, 5 points if their initial score is within 0–24 on the Berg Balance Scale [5]. The changes noted in average patient BERG score (22.1) in this study from Day 1 to 2 years testing conclusively demonstrate (95% confidence) that true change and marked improvement in gait and balance occurred. Additionally, these patients improved from a high fall risk to a medium fall risk status.

Imaging

On MRI, the average Evan's Ratio was essentially unchanged throughout the study, recorded as 0.34 on Day 1 and 0.34 at 2 years of follow up. This indicated an unchanged size ratio of the maximal ventricular width divided by the maximum width of the inner table of the cranium. In this study, the Evan's Ratio was recorded by selected neuro-radiologists, again suggesting satisfactory congruity.

The MRI posed no potential threat for valve related complications or disturbances in these patients and did not require additional clinical investigation for any instance of neuro deterioration.

Cognitive

The Average Total Screening Index of the NAB indicated a 15.5 point improvement in patient scores from 77.5 on Day 1 to 93 at 2 years of follow up. These scores demonstrate improvement from a "mildly impaired" interpretive category to "average" [6]. The standard deviation for improvement is approximately 15 points [7].

The one patient who required a shunt revision noted a gradual decline in cognitive function shortly after her improved 1 year evaluation. Unable to now stand or ambulate unassisted, her incontinence had also returned. X-Ray Shunt Series was unremarkable. The patient was then taken to surgery where the valve was found to be obstructed. A different valve system was placed.

The lack of any other post-operative complications such as over drainage or subdural effusion suggests efficiency of this flow regulated valve system in patients with INPH. The exceptional outcome in this small group of patients speculates paralleled success in a larger group of patients. Data for a larger, prospective comparative study are currently being reviewed.

Conclusion

Objective improvement in BERG and NAB appears to provide conclusive evidence of efficacy in this small group of patients with INPH treated with placement of an LFV and followed for two years. The absence of over-drainage as a related complication in this small group is encouraging. Documentation of progressive improvement and stability in objective measurements (BERG and NAB) is important. The ease of use and limited follow up post operatively are desirable and may compare favorably to the management necessary for maintenance of a differential pressure valve system. A larger prospective randomized study is under way to fully delineate salient differences in the efficacy of a Differential Pressure or Flow Regulated Valvular device in the treatment of INPH.

Disclosure

The authors report no financial or personal interest with Integra Life Sciences.

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